UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,296	06/02/2005	Manuela Guglielmo	5002-1074	8261

466 7590 01/20/2010

YOUNG & THOMPSON
209 Madison Street
Suite 500
Alexandria, VA 22314

EXAMINER	
GULLEDGE, BRIAN M	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
01/20/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/537,296	GUGLIELMO ET AL.	
	Examiner	Art Unit	
	Brian Gulledge	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 26 October 2009 and 27 November 2009 have been entered.

Previous Rejections

Applicants' arguments, filed 27 November 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 recites a composition that comprises "active

ingredients" as one component, and the composition also comprises panthenol as another component. The term "active ingredients" is then defined as *consisting* of four species, including glutamine peptides. The specification discloses that the glutamine peptides (one of the four "active ingredients" recited) support the octyl butyrate by acting as an energy supplement for cells undergoing multiplication (page 7, lines 12-15). However, the declaration filed on October 26, 2009 states that the glutamine peptide provide an essential energy source (page 7, first paragraph), and the panthenol also acts as an energy supplement, backing up the role of the glutamine peptides (page 7, second paragraph). Thus, panthenol has the same activity as the glutamine peptide. It is thus unclear what is encompassed by the claim, which recites that the composition consists of four active ingredients, but also recites an additional active ingredient in the composition with the same mode of action.

For examination with regards to the prior art, the Examiner is taking the term "active ingredients" to be shorthand for referring to the four species of octyl butyrate, glutamine peptides, monomethylsilanol-hydroxyproline aspartate, and benzyl nicotinate. The composition, which *comprises* the recited ingredients, is considered to encompass compositions that contain additional bioactive agents and pharmaceutical agents other than those four instantly recited.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desjonqueres (US Patent 6,001,378) in view of Greff (FR Patent Publication 2,740,331) and

Hino et al. (US Patent Application Publication 2003/0003072). Greff is in a language other than English (French). As such, the rationale for this rejection will reference the provided machine-generated English-language translation.

Desjonqueres discloses compositions for treating hair loss, the compositions comprising organosilicone derivatives (abstract, lines 1-9). Suitable silanol derivatives disclosed by Desjonqueres include the complex of hydroxyproline and aspartic acid with methylsilanol (column 4, lines 14-19). Amounts taught by Desjonqueres range from 0.1 to 1.0 wt% (column 6, examples 1-3), a range that overlaps the instantly recited range. And in cases involving overlapping ranges, the courts have consistently held that even a slight overlap in range establishes a *prima facie* case of obviousness. *In re Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Desjonqueres also discloses that the composition is applied topically (column 5, lines 45-54). Desjonqueres does not teach the further inclusion of octyl butyrate, glutamine peptides, benzyl nicotinate, and panthenol in the composition, as recited by instant claim 8.

Greff teaches compositions for treating hair comprising from 0.02 to 1 wt% octyl butyrate and from 0.1 to 1 wt% of cereal protein hydrosate rich in glutamine (claim 5). The ranges taught for the amounts of the two ingredients overlap the instantly recited ranges. Greff further teaches using this composition as a treatment against the loss of hair (claim 10). Greff does not teach the inclusion of a complex of hydroxyproline and aspartic acid with methylsilanol, benzyl nicotinate, or panthenol in the composition, as recited by instant claim 8.

Hino et al. discloses compositions for promoting hair growth (title). Hino et al. teaches that vasodilators such as minoxidil or benzyl nicotinate can be the pharmaceutically active component of the invention (paragraph [22], lines 1-3). The vasodialating active agent is present

in from 0.05 to 2 wt% (paragraph [28], lines 1-3). Hino et al. additionally discloses that other useful compounds for inclusion in the composition include the metabolism activator panthenol (paragraph [24], lines 1-10), and Hino et al. teaches using these ingredients in from 0.01 to 2 wt% (paragraph [25], lines 1-4). The ranges taught for the amounts of the two ingredients overlap the instantly recited ranges. Hino et al. does not teach the inclusion of a complex of hydroxyproline and aspartic acid with methylsilanol, octyl butyrate, or glutamine peptides in the composition, as recited by instant claim 8.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the three topically applied compositions taught by Desjonqueres, Greff, and Hino et al. to form a single composition, useful for treating the loss of hair. Generally, it is *prima facie* obvious to combine compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06.

Instant claim 9 recites the addition of perfumed substances and preservatives, instant claim 10 recites the inclusion of ethyl alcohol, water, menthol, and preservatives, and instant claims 14-15 recite the inclusion of the ingredients recited by instant claim 8 as well as preservative. The formulations Desjonqueres discloses include preservatives, perfumes, and water (column 6, examples 1-3), as well as ethanol (example 3). Greff also teaches the inclusion of ethyl alcohol, preservatives, perfume, and water for the composition (page 6, example 3). And Hino et al. discloses the use of menthol (paragraph [24], line 24).

Instant claims 11-13 recite the inclusion of hydroxyproline and aspartic acid instead of monomethylsilanol-hydroxyproline aspartate. Desjonqueres discloses the use of methylsilanol aspartate hydroxyproline, and monomethylsilanol-hydroxyproline aspartate is a complex of the two amino acids hydroxyproline and aspartic acid (instant specification page 5, lines 32-34), and thus the composition disclosed by Desjonqueres comprises the two amino acids aspartic acid and hydroxyproline.

Declarations Filed Under 37 CFR 1.132

The declaration filed on 14 October 2009 under 37 CFR 1.132 is acknowledged. The Applicant argues that the data presented in the declaration demonstrates superior properties of the inventive composition that are not recognized by the prior art. The data presented therein is not found persuasive for overcoming the above prior art rejection. Several experiments are presented. The first experiment demonstrates the effectiveness of a composition comprising octylbutyrate and a glutaminpeptide ("composition A") as compared to a placebo. The data presented demonstrates that "composition A" promotes more of the hair to be in the active (telogen) phase, as compared to the placebo, and there was a reduction in hair loss after 90 days. This would be expected, as octyl butyrate and glutamine peptides are known for the reduction of hair loss (see Greff, discussed above).

The second experiment tested a composition comprising octylbutyrate, glutaminpeptide, monomethylsilanol-hydroxyproline asparatate, benzyl nicotinate, and panthenol ("composition B"). Those using this composition had a reduction of hair loss after 30 days and after 60 days: however, no control experiments were provided as a comparison. But "composition B" would be

expected to reduce hair loss, as each of the disclosed ingredients are known for treating hair loss (see Desjonqueres, Greff, and Hino et al., as discussed above).

As for the conclusion that "composition B" exhibits unexpected superior results to "composition A," the Examiner does not agree. The data compare the results of "composition B" after 30 and 60 days, but no later, whereas the results for "composition A" are only disclosed after 90 days. There is no data presented to demonstrate the effect of each composition after the same length of time of administration. Additionally, the amount of hair loss measured for "composition B" after 30 days was 65%, and after 60 days the amount was 70%. For "composition A," the decrease of hair loss after 90 days was 67%. Thus, it appears that "composition A" achieves the approximately the same reduction in hair loss as "composition B." Data for the other tests performed (wash test & pull test) was not provided for "composition A" and as such no comparative conclusion can be determined.

The declaration filed on 23 October 2009 under 37 CFR 1.132 is acknowledged. The declaration explains the properties of the individual components, and the aim of the invention. No secondary considerations appear to be presented in this declaration that would relate to, or potentially overcome, the above rejections.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gulledge whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday 6:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BMG

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612